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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,419

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Alain H. Curaudeau

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EXAMINER

LEE, WILLIAM Y

ART UNIT

PAPER NUMBER

1629

NOTIFICATION DATE

DELIVERY MODE

01/09/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP.Docketing@aporter.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,419	CURAUDEAU ET AL.	
	Examiner	Art Unit	
	WILLIAM LEE	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/11/2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,6-9,11-13,18,19 and 22-30 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,6-9,11-13,18,19 and 22-30 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the claims

Claims 1, 6-9, 11-13, 18, 19 and 22-30 are presently pending.

Withdrawn claim rejections under 35 U.S.C. §112, second paragraph

In response to applicants' response and/or amendment to claims 1-9, 11-13, 18, 19 and 22 to specifically recite particular photosensitizer compositions, the rejections of claims 1-9, 11-13, 18, 19 and 22 under 35 U.S.C. §112, second paragraph is now withdrawn.

Withdrawn claim rejections under 35 U.S.C. §112, first paragraph

In response to applicants' response and/or amendment to claims 1-9, 11-13, 18, 19 and 22 to specifically recite particular photosensitizer compositions and particular gland disorders, the rejections of claims 1-9, 11-13, 18, 19 and 22 under 35 U.S.C. §112, first paragraph is now withdrawn.

Maintained claim rejections - 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 11-13, 18, 19, 22 and 23 are obvious over QLT and Kalka

The rejection of claims 1-9, 11-13, 18, 19, 22 and 23 under 35 U.S.C. 103(a) as being unpatentable over QLT Inc. WO 03/039597 A1 (hereinafter "QLT") in view of Kalka et al J Am Acad Dermatol, Mar 2000 (hereinafter "Kalka") **is maintained**.

Applicants' traversal of the obviousness rejection over QLT in view of Kalka is based on the following. On page 6 of their response to the non-final office action, applicants state that their claims are directed to methods for treating recited hyperactive sebaceous gland disorders in a subject in need thereof, the method comprising topically applying a photosensitizer composition to skin tissue of said subject exhibiting symptoms of a hyperactive sebaceous gland disorder and exposing the tissues of said subject to light energy. Applicant's quote the Examiner that it would have been obvious to those skilled in the art to employ methods of treating hyperactive sebaceous gland disorders "motivated by the teaching of Kalka and QLT Inc. that teach both psoriasis and seborrhea are well known to be treated with porphyrins and light energy." Office Action issued June 10, 2011 at page 13.

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In support of the traversal, applicants allege that Kalka does not in fact teach the treatment of the claimed hyperactive sebaceous gland disorders by topically applying a photosensitizer composition to skin tissue of a subject in need thereof and exposing the tissue of the subject to light energy, as required by the claims.

Applicants allege that Kalka merely alleges the destruction of lipophilic propionibacteria (i.e., a cause of acne) for management of acne vulgaris via use of blue light, and a resultant reduction in both acne and seborrhea.

Applicants states that Kalka does suggest photodynamic therapy (PDT) for benign inflammatory skin diseases.

Applicants deny stating that Kalka teaches the destruction of lipophilic propionibacteria with **porphyrins** for management of acne vulgaris via use of blue light. It is respectfully suggested that applicants do quote Kalka for the use of porphyrins and their role in the photodynamic destruction of micro-organisms associated with acne vulgaris.

Applicants quotes Kalka for the statement, "[t]he production of porphyrins by lipophilic propionibacteria has been utilized for photodynamic destruction of these micro-organisms for the management of acne vulgaris." Kalka at page 403. Applicant's state that Kalka appears to be referring to the native production of porphyrins by lipophilic propionibacteria *in vivo*, and the utilization of production of such for destruction of the micro-organisms. It is noted that Kalka does state that "repeated illumination with blue light at a cumulative dose of 325 J/cm² resulted in a marked of both acne and seborrhea", page 403.

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Applicants' conclude that nothing in QLT or Kalka teaches or suggests a method with an intent to treat the recited hyperactive sebaceous gland disorders, **by topically applying** a photosensitizer composition to skin tissue of a subject in need thereof.

In response, the teachings of Kalka are rife with the suggestion that photosensitizing chemicals are topically applied in conjunction with light energy for the treatment of various skin diseases. Kalka teaches that for years, topical photosensitizers (psoralen and eosin) have been used to treat various skin disorders (page 389, columns 1 and 2). In fact Kalka teaches an approach to avoid the cutaneous accumulation of porphyrin-based photosensitizing drugs (such as intravenous porfimer sodium) and their slow clearance from skin, is the use of topical drug formulations (page 391, column 2). Kalka references in its endnotes 52-55, the McCullough, Meffert, Pres and Steiner references that all describe studies of topically applied porphyrin photosensitizers (see page 407, endnotes 52-55). Further, Kalka teaches topically applied porphyrin-like compounds δ -aminolevulinic acid (ALA) and porphines (pages 391-392). Further, QLT makes numerous references to topically applied, porphyrin-like photosensitizers for its method of treating skin disorders as claimed by applicants, (see page 2, lines 1-5; Summary of Invention, page 2; and so forth).

With regard to applicants' amendment to specifically recite sebaceous gland disorders directed to seborrhea, seborrheic dermatitis, sebaceous gland hyperplasia and combinations thereof, it is respectfully pointed out that Kalka not only provides the teaching and suggestion of porphyrins for the treatment of seborrhea (at page 403,

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column 2), Kalka teaches that the application of porphyrin-derivative ALA leads to accumulation of PpIX (another porphyrin-like compound) in sebaceous glands, and therefore the disorders associated with sebaceous glands (page 403, column 1, bottom page).

Therefore, Kalka not only provides the teaching, suggestion and motivation to one of ordinary skill the art to topically apply porphyrin derivatives such as ALA, Kalka also teaches that application of ALA leads to accumulation of PpIX in sebaceous glands, have applicants have targeted with their claimed method of treatment.

Thus contrary to applicants' response to the obviousness rejection of claims 1-9, 11-13, 18, 19, 22 and 23, the combined teachings of QLT and Kalka render these claims obvious. A reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi*; 215 USPQ 569 (CCPA 1982). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. § 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Accordingly, the rejection of claims 1-11 for being obvious over QLT and Kalka is proper and is maintained.

Reiterated rejection

Applicants contend that Kalka does not in fact teach the treatment of hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof and exposing the tissue of the subject to light energy, as required by the claims. Applicants are further of the opinion that, Kalka mentions that "lipophilic propionibacteria has been utilized for photodynamic destruction of these micro-organisms for the management of acne vulgaris. Repeated illumination with blue light at cumulative dose of 325 J/cm^2 resulted in marked reduction of both acne and seborrhea. [...] The possible value of topical PDT for benign inflammatory skin disease need further exploration", see Kalka, page 403. Applicants states that Kalka teaches the destruction of lipophilic propionibacteria with **porphyrins** for management of acne vulgaris via use of blue light, and a resultant reduction in both acne and seborrhea. Kalka then suggests the possible value of PDT for benign inflammatory skin diseases and suggests further exploration (page 403, second column). Applicants believe that one of ordinary skill in the art would need to modify the teachings of QLT and Kalka so as to specifically treat hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof.

The Examiner respectfully disagrees as applicants' remarks are misplaced. As previously stated, QLT Inc. teach a method of treatment of atopic dermatitis (page 15, lines 1-2, claim 13), and psoriasis (page 14, lines 28-30, claim 13) comprising administering a **photosensitizing agent** and **light energy** (page 2, lines 10-23). The photosensitizers will absorb radiation in the range of from 400 nm to 800 nm (page 3, lines 14-16) and include green porphyrins (page 3, line 31) such as the preferred BPD-MA (**verteporfin**) (page 4, lines 15-16) and QLT0074 (**lemuteporfin**) (page 6, lines 4-7). QLT Inc. teach treatment of psoriasis and atopic dermatitis but is silent with regard to treatment of seborrhea, seborrheic dermatitis or sebaceous gland hyperplasia.

Kalka et al. teach treatment of disorders such as **seborrhea** with porphyrins and illumination with blue light (page 403, column 2) and treatment of psoriasis with photodynamic therapy (PDT) using **photosensitizers** such as BPD-MA (**verteporfin**) (page 402, column 1). Applicants concede that Kalka teaches the treatment of both acne and seborrhea. As explained above, sebaceous gland activity and the formation of acne go hand in hand as acne results from the obstruction and blockage of hair follicles and accompanying sebaceous gland by plugs of sebum produced by said gland.

Applicants suggest that Kalka does not teach topical application of a photosensitizer. In response to this suggestion, it is noted that QLT teaches topical application of photosensitizers BPD-MA (**verteporfin**) and QLT0074 (**lemuteporfin**). Per MPEP 2145, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Further, Applicants have added the negative limitation to exclude the treatment of acne from their claimed method. The pathogenesis of acne involves the “formation of comedones, papules, pustules, nodules, and/or cysts as a result of **obstruction and inflammation of pilosebaceous units** (hair follicles and their **accompanying sebaceous gland**). . . . Acne occurs when **pilosebaceous** units become obstructed with plugs of **sebum** [produced by sebaceous glands] and desquamated keratinocytes. . . . “ See The Merck Manual For Healthcare Professionals, section Acne Vulgaris (online version, www.merckmanuals.com/professionals, accessed June 2, 2011). Applicants’ specification describes acne as an example of a hyperactive sebaceous gland disorders (page 3, lines 20-21). Applicants also describe and define other non-acne disorders to be treated (seborrhea, seborrheic dermatitis, or sebaceous gland hyperplasia) (page 3, lines 30-31). Sebaceous gland activity and the formation of acne go hand in hand with each other; acne results from the obstruction and blockage of hair follicles and accompanying sebaceous gland by plugs of sebum produced by said gland.

Due to the related nature and pathophysiology of acne and hyperactive sebaceous gland disorders, it would be obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Kalka with that of QLT to render the claimed invention obvious. Thus contrary to applicants belief, the combined teachings of QLT and Kalka read upon the claimed invention as taught in the preamble and body of claim, i.e., the method of treating hyperactive sebaceous gland disorders, other than

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acne, by topically applying a photosensitizer composition to the skin of a subject in thereof.

With regard to motivation, applicants contends that nothing in QLT or Kalka teaches, suggests the claimed method; further, applicants contend that absent a teaching or suggestion of their method, one of ordinary skill in the art would find no motivation to perform the claimed method for treating hyperactive sebaceous gland disorders, **other than acne**. On the contrary, sebaceous gland activity (formation of sebum) and the formation of acne go hand in hand as acne results from the obstruction and blockage of hair follicles and accompanying sebaceous gland by plugs of sebum. One of ordinary skill in the art would be motivated to attempt to treat sebaceous gland activity disorders as it relies upon the same basic etiology as the formation of acne on the skin of a subject so afflicted.

Accordingly, it is clear that QLT in view of Kalka renders the claimed method obvious at the time of invention. Therefore, the rejection is maintained.

Claims 24-30 are obvious over QLT and Kalka

Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over QLT in view of Kalka.

The teachings of QLT and Kalka previously discussed in this office action and throughout the prosecution of this case are hereby incorporated herein.

Claim 24 is directed towards the method of claim 23, wherein the composition has a viscosity at 20 °C of from about 50 cps to about 50000 cps. Addressing instant

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claim 8, drawn to a viscosity at 20°C of from about 50 cps to about 50000 cps, QLT teaches a viscosity of from about 50 cps to about 50000 cps at 20° C (page 9, lines 24-27).

Claim 25 is directed towards the method of claim 23, wherein excess photosensitizer composition is removed from the skin prior to application of activation energy. Addressing instant claim 9, drawn to the method wherein excess photosensitizer is removed from the skin prior to application of energy, QLT teaches that the composition is washed after allowing time for the photosensitizer to penetrate the stratum corneum and then irradiated with activation energy at an appropriate wavelength (page 12, line 20 to page 13, line 11).

Claim 26 is directed towards the method of claim 23, wherein steps i) and ii) are repeated at least about once every six months; Claim 27 is directed towards the method of claim 23, wherein steps i) and ii) are repeated at least about once every three months; Claim 28 is directed towards the method of claim 23, wherein steps (i) and (ii) are repeated at intervals of not less than about 5 days. Addressing instant claims 11-13, drawn to repeat of steps i and ii about every 6 months, about every 3 months and not less than about 5 days, QLT is silent as to how often the treatment method is repeated. However, one having ordinary skill in the art at the time the invention was made would be motivated to repeat the treatment as necessary. Since QLT teaches a treatment and not a cure, it is prima facie obvious to repeat the treatment as necessary and it is within the purview of the artisan to determine and optimize the period between doses.

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Claim 29 is directed towards the method of claim 23, wherein said energy is at least in part supplied by a light emitting diode device. Claim 30 is directed towards the method of claim 29, wherein said device emits red and blue light. Addressing instant claims 29 and 30 drawn to an energy that is supplied by a light emitting diode device and the device emits red and blue light, Kalka teaches that diode lasers are employed to produce red light in the range of 770 to 850 nm (page 395, column 1) and teaches that photodynamic management of dermatologic conditions is simplified by the accessibility of the skin to light application and leaves the option to use any light device with the appropriate spectrum corresponding to the absorption maximum of the photosensitizing compound (page 394, column 2). Further, QLT teaches use of any suitable light source to activate the photosensitizer (page 1, lines 9-14) and teaches that photosensitizers generally absorb radiation in the range of from 400 nm (about the range of blue light) to 800 nm (about the range of red light) (page 3, lines 14-16).

As stated above and quoting *In re Opprecht*, *In re Bode*, *In re Fracalossi*; a reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. § 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the

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time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusions

No claim is allowable.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM LEE whose telephone number is (571)270-3876. The examiner can normally be reached on M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S.

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Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/WILLIAM LEE/
Examiner
Art Unit 1629

/Jeffrey S. Lundgren/

Supervisory Patent Examiner, Art Unit 1629